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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,547	01/26/2004	Seung-Hak Choi	YPL0077US	1634

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EXAMINER	
ZHOU, SHUBO	

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
03/08/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/765,547	CHOI ET AL.	
	Examiner	Art Unit	
	SHUBO (Joe) ZHOU	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendment

Applicant's amendment filed 12/3/09 is acknowledged and entered.

Status of the Claims

Claims 1-14 are currently pending and under consideration.

Claim Rejections - 35 USC § 101

The rejection of claims 12-14 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendment filed 12/3/09, where the claimed process is tied to a computer processor of the client system, which is a particular machine/apparatus.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborne et al. (IDS document: Artificial Intelligence System for Genetic Analysis, WO 01/16860 A2, March 8, 2001).

This rejection is reiterated from the previous Office action.

The claims are amended to be drawn to a method or a server-client network system for genotyping analysis on a target sample. The network comprises a server including an analysis algorithm database for the genotyping analysis and a client system communicatively coupled to the server, which receives the results of a biochip test on the target sample, identifies a biochip on the target sample, selects and downloads an analysis algorithm for the chip, performs the genotyping analysis and stores and output the results to a user, wherein the selected algorithm is established using statistical data for results of performing testing on a number of patient and reference samples using the biochip.

Absent an explicit definition in the specification, the term "analysis algorithm" is interpreted as any algorithms for any analysis.

With regard to at least independent claims 1 and 12, Osborne et al. disclose a network system and a method for genetic analysis. The network system comprises a server that includes multiple databases required for the genetic analysis, which are provided to client that receives the results of a microarray analysis and performs the genetic analysis. See at least Fig. 1 and pages 4-6. The genetic analyses include analysis of genomic mutations (see page 12, lines 30-31), which is interpreted as a type of genotyping. Osborne et al. disclose that the system comprises central data processing facilities and user facilities and that "each user facility may include an optical scanning system to collect hybridization signals from a nucleic acid array, an image processing system to convert the optical data into a set of hybridization parameters, a connection to a data network, and a user interface to display, manipulate, search, and analyzed hybridization information." See page 5. The system comprises various types of users at different tiers including remote users/local users, web users/internet users, diagnostic users including diagnostic master users, and browser users (see pages 10-12), any and all of which is interpreted as being part of the client system as recited in the instant claims. Since the user facilities (interpreted as client) and the central data processing facilities (interpreted as server) comprising the databases are linked by encrypted network connections (see page 5), it is interpreted that the databases in the server are provided to the client and that the client system is communicatively coupled to the server.

Furthermore, Osborne et al. state on page 12:

> There are two categories of diagnostic users, such as "diagnostic master users" and "diagnostic users". Accounts for diagnostic master users are authorized and correspond to the user sites where the systems are deployed. These diagnostic master users are allowed to authorize accounts for diagnostic users. For clinical

> applications, diagnostic users correspond to the individuals that have been tested. For research and development applications, diagnostic master users can designate either individual chip test results or groups of chips as a single diagnostic user, wherein this option lies with the diagnostic master users in order to meet their testing and analysis needs. Diagnosis processing is a key part of the artificial intelligence system. The diagnosis processing for clinical applications may be different from that of research and development applications. Diagnosis processing for clinical applications implements a rules-based analysis application which utilizes a database set of rules and results. Diagnosis processing thereby determines which conditions apply to the various combinations of gene expression levels and personal medical history.

The accounts authorized to diagnostic users are also interpreted as part of the client system as the accounts correspond to the user sites. Additionally, this statement clearly indicates that for a diagnostic user, i.e. client, to perform the diagnosis processing, the user first receives (i.e. downloads) the systems because they "are deployed," and the system includes databases of rules, etc., which are interpreted as analysis algorithms.

With regard to the limitation of identifying the biochip for the target sample, while Osborne et al. do not explicitly disclose identifying the biochip for the target sample, the databases in the server disclosed by Osborne et al. include database for chip ID and pattern/lay-out, analysis algorithm and a quality control database. See at least Fig. 1 and pages 5-7, 10, 12-14, and 27. See also pages 19-22 for rules/algorithm for analysis in the system. Because the algorithm is for analysis of the biochip data and the biochip has identifier, it is interpreted the chip ID is to be used for identifying the chip (biochip

Osborne et al. do not explicitly disclose that the analysis algorithm is established using statistical data for results of performing testing on a number of patient and reference samples using the biochip.

However, it would have been obvious to one having ordinary skill in the art that in order for Osborne's rules to be used by users for the analysis of diagnostics, or any rules for anybody to use for diagnostic analysis of a disease, such rules would have been established on the basis of previous test or diagnostic results on patients and compared with normal individuals using statistical data and tests.

With regard to claims 2 and 13, the databases in the server disclosed by Osborne et al. include database for chip ID and pattern/lay-out, analysis algorithm and a quality control database. See at least Fig. 1 and pages 5-7, 10, 12-14, and 27. See also pages 19-22 for rules/algorithm for analysis in the system. Because the algorithm is for analysis of the biochip data and the biochip has identifier, it is interpreted as the algorithm is relevant to the biochip identifier in view of the indefiniteness of the limitation set forth above.

With regard to claims 3-4, the server of the system by Osborne et al. comprises database that is built up from statistical data for the results of test on a number of patients and references samples using microarrays. Osborne et al. disclose that the database server stores hybridization profiles, patient profiles, reference information, clinical information associated with hybridization profiles, and statistical summaries. See page 5. Osborne et al. further disclose that "hybridization profiles collected by remote and/or local facilities include clinical observations or other information associated with each profile, and the profile with associated observations is added to the central database." See page 6. Osborne et al. also state that "the databases of the instant invention continually mature and develop into more and more complex systems as information from public and private sources continues to be added to the existing database." See pages 13 and 15. Thus, the databases are being built up while the users use the system.

With regard to claim 5, in the system disclosed by Osborne et al., the users/clients comprise optical scanning system and identifier recognizer. See at least Fig. 1 and pages 11 and 16.

With regard to claims 6-8 and 14, which include limitations that the client comprises an engine for performing a series of logical functions, in the system disclosed by Osborne et al., the client comprises an engine or means for performing a function of detecting the identifier of the biochip (see Fig. 1 and the "application ID on at least page 16, array ID and array location ID on at least pages 26-27, and sample ID, patient ID, etc. on pages 28-29). Client can select and download data/database based on application ID, etc., and perform genotyping analysis. See the diagnostic architecture listed on pages 16-18. Furthermore, with regard to claim 8, the method of Osborne et al. allows client to perform the genetic analysis including reading results via scanning system, (see pages 16-18), linking results with spot position information of the chip, etc. (see pages 13-14, where the database queries include chip ID genetic pattern, pattern match, result output, etc. and page 15). Users can perform functions such as correlating the hybridization signals of one or more probes and creating test hypothesis relating to a particular pathological or physiological condition, using the server databases to search, correlate, manipulate and display existing data, etc. See page 15.

With regard to claims 9-11, which are drawn to computer readable medium comprising computer executable instructions for executing the method steps and functions performed by the system above, given that the system for performing the functions and method steps as set forth above is a web-based computer systems including server and client, it would be readily recognized by one skilled in the art that the system

inherently comprises computer readable medium containing computer executable instructions for performing the functions.

Applicant's arguments filed 12/3/09 have been fully considered but they are not found persuasive.

It appears that applicant's arguments are focused on the newly amended limitation "genotyping analysis algorithms" as evidenced in the bolded presentation thereof in the response on page 11, etc., and centered on the argument that Osborne does not teach or suggest the client system selecting and downloading the genotyping analysis algorithms. See pages 11-13 of the response. This is not unpersuasive. First, since there is explicit definition in the instant disclosure for the newly added term "genotyping analysis algorithm," it is interpreted to include any algorithms used for and in the process of genotyping analysis. Secondly, as set forth in the previous Office actions, Osborne et al. clearly disclose that their invention provides "a complete system" and databank for array analysis and clinical analysis. The system includes neural network algorithms among other things. See page 4. Osborne et al. also disclose that "[i]n another manner of practicing the invention, users perform statistical tests on cataloged hybridization profiles stored in the central data processing facility ... users create and test hypothesis relating hybridization information to particular pathological or physiological states. Clearly, this would be done in a system like the web or internet. A variety of statistical analyses are provided to suggest and evaluate hypothesis" (see page 6, emphasis added by the Office). Since the system of Osborne et al. is an artificial intelligent system with neural network algorithms, etc., it would have been obvious to one having ordinary skill in the art that these "variety of statistical analyses" that are provided "to suggest and evaluate

hypothesis" are algorithms for the analysis, which are thus analysis algorithms, and if the analyses are for hybridization, microarray data and genotyping, these algorithms are broadly interpreted as genotyping analysis algorithms, again absent a clear definition for the term in the disclosure. Further, if they "are provided," they must be provided to a user of the system of Osborne et al including the rules or algorithms in the database. As also set forth in the previous Office action, Osborne explicitly disclose that for one application, accounts for diagnostic master users are authorized and correspond to the user sites where the systems are deployed; that for research and development applications, diagnostic master users can designate either individual chip test results or groups of chips as a single diagnostic user, wherein this option lies with the diagnostic master users in order to meet their testing and analysis needs, and that diagnosis processing is a key part of the artificial intelligence system and the diagnostic processing for clinical applications implements a rules based analysis application which utilizes a database set of rules and results. It would have been obvious to one having ordinary skill in the art that if the systems including all the algorithms are deployed, they must have been provided to the users and the algorithms are downloaded in the broad sense of the word.

Given the relatively large number of responses and Office actions in the prosecution of the application, and the apparent lack of interviews between applicant and the examiner, if applicant believes an interview would result in overcoming the rejection and find allowable subject matter, he or she is strongly urged to arrange for such interview with the examiner.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL.

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Shubo (Joe) Zhou/

SHUBO (JOE) ZHOU, PH.D.

PRIMARY EXAMINER